Appl. No.: 10/588,428 Filing Date: August 4, 2006

### **REMARKS**

Claims 1, 2 and 5-7 are pending in the present application. Entry of the amendment to Claim 1 set forth in Applicants' After-Final Amendment dated November 25, 2009 is respectfully requested. No further amendments are requested herein. Reconsideration and withdrawal of the present rejections in view of the comments presented herein are respectfully requested.

## Rejection under 35 U.S.C. § 103(a)

The rejection of Claims 1, 2 and 5-7 as allegedly being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.*. 46:3875-3878, 1998) and Xia (CN1435125; Derwent Acc No 2004-023802) in view of Suzuki et al. (*J. Agric. Food Chem.* 48:5649-5653, 2000) and in further view of Iwasaki et al. (US 7,014,876) was maintained.

The pending claims recite a method of reduction of triglyceride levels by administering a functional beverage (claim 1) or composition (claim 6) comprising the recited methylated catechins and extracted from the recited list of tea leaves. The present invention relates, in part, to Applicants' discovery that methylated catechins are unexpectedly much better than non-methylated catechins at reducing triglyceride (TG) levels. Based on this unexpected discovery, they identified the varieties of tea listed in Claims 1 and 6 that have high levels of methylated catechins, and selected these teas for reducing triglyceride levels. Nothing in the prior art would lead one of ordinary skill in the art to select the presently claimed types of teas.

## Zeyuan et al. (J. Agric. Food Chem., 46:3875-3878, 1998)

Neither of the two primary references, Zeyuan et al. and Xia, discloses or suggests methylated catechins. The Examiner alleges that since Zeyuan et al. teaches that black and green tea extracts reduce blood triglycerides (BTG), it would have been obvious that any of the constituents of both green and black tea have BTG reducing effects.

Zeyuan et al. discloses the following:

- a) Green tea and black tea extracts have an effect of reducing the content of BTG, but are not dose-dependent (see p. 3876 at line 2 from the bottom of left column to line 2 from the top of right column).
- b) Table 2 shows analysis data on amounts of various catechins contained in 0.6, 1.2, and 2.4 g of green tea and black tea per 100 mL of water extract. Table 2 shows that, as the quantity of the green tea or the black tea increases, the amount of catechin extract also increases.

Appl. No.: 10/588,428 Filing Date: August 4, 2006

c) Table 3 shows a BTG reducing effect resulting from consumption of 0.6, 1.2, or 2.4 g of green tea or black tea per 100 mL of water extract. Tables 2 and 3 show that the amount of catechins in the extract does not correlate with the BTG reducing effect.

Thus, Zeyuan et al. do not indicate which substance in the extract has a BTG reducing effect. In addition, since the amount of catechins in the extract does not correlate with a BTG reducing effect, a person of ordinary skill in the art would not expect that catechins would contribute to the reduction of BTG.

## Xia (CN 1435125)

Xia relates to a health-care food that is able to reduce the content of blood low-density cholesterol and glyceride levels. A partial English translation of Xia was provided with Applicants' previous response. However, this partial translation was not admitted by the Examiner, since only a portion of the disclosure was provided. Enclosed herewith as Exhibit A is an English translation of the entire CN 1435125 document, along with a Declaration by the translator. Example 1 of Xia describes that consuming polygonum multiflorum and hawthorn extract, as well as a health-care food which is a mixture of oolong tea, Auricularia auricula-judae, and malt powders, reduced cholesterol. However, Xia merely describes that "[t]he health product can effectively reduce the content of low-density cholesterol and triglyceride in the human blood to make them below the normal value." (page 4, last paragraph), without providing any evidence whatsoever. Based upon this disclosure, a person of ordinary skill in the art would not know which substance in this health-care food has the recited cholesterol and triglyceride-lowering effect. Example 1 of Xia merely notes that blood-fat can be reduced. Although Examples 2 and 3 describe compositions that include the health-care food, no effects of the composition are described. In addition, although the health-care food of Xia contains oolong tea and four other substances, the specific effect of the oolong tea is not described or suggested. Moreover, the oolong tea of Xia is a tea leaf powder, not an extract as recited in the present claims. Even if the tea leaf powder is consumed, only a minute amount of methylated catechin can be extracted in the human body. Thus, Xia does not disclose or suggest a relationship between oolong tea and the reduction of BTG, and therefore does not suggest that methylated catechins would reduce BTG.

Appl. No.: 10/588,428 Filing Date: August 4, 2006

# Suzuki et al. (J. Argic. Food Chem. 2000, 48, 5649-5653)

Suzuki et al. disclose that EGCG3"Me and EGCG4"Me extracted from oolong tea leaves of Benihomare cultivar have anti-allergy effects. However, this reference neither teaches nor suggests that EGCG3"Me and EGCG4"Me have BTG reducing effects.

### Iwasaki et al. (US 7,014,876)

Iwasaki et al. describe a packaged beverage containing various catechins in an amount of 0.092 to 0.5 g/100 mL, and that green tea and oolong tea are employed as tea leaves. However, this reference does not disclose that BTG levels are reduced by consuming a beverage containing 5 mg or greater/100 mL of methylated catechins according to present claim 1.

## Nonobviousness over the cited combination of Zeyuan, Xia, Suzuki and Iwasaki

Although each of Zeyuan et al. and Iwasaki et al. discloses catechins extracted from tea leaves, the methylated catechins recited in the present claims are specific catechins which are present in large quantities in the specific tea leaves recited in the present claims, and these methylated catechins differ from the catechins described in Zeyuan et al. and Iwasaki et al. Based upon the disclosure of Zeyuan et al., a person of ordinary skill in the art would realize that catechins do not contribute to BTG reduction. Xia discloses the use of oolong tea powders as a component of a health-care food; however, Xia does not describe the relationship between oolong tea and BTG reduction, let alone suggest BTG reduction by the use of methylated catechins. Suzuki et al. do not disclose any relationship between methylated catechins and BTG reducing effects.

Thus, the combination of references cited by the Examiner does not teach or suggest the use of the claimed methylated catechins for reduction of BTG levels. Consequently, since one of ordinary skill in that art would not have adjusted the amount of the methylated catechins to those appropriate for BTG reduction, one could not have arrived at the appropriate amount of the methylated catechin (5 to 30 mg/100 mL as presently claimed). The Examiner alleges that appropriately adjusting the amount of methylated catechin would be obvious. However, since none of the cited references disclose or suggest that the claimed methylated catechins have a superior BTG reducing effect compared to ordinary catechins, the adjustment of the amount of methylated catechins to those recited in the present claims would not have been obvious.

Thus, now that the translation of Xia must be considered, it is clear that in the absence of the inventors' teachings, one having ordinary skill in the art would not have any reason to select the

Appl. No.:

10/588,428

Filing Date:

August 4, 2006

particular varieties recited in the present claims out of all the many varieties of tea, or to select the recited methylated catechins at the recited levels, because such a person would not know to select the varieties that have high levels of methyl catechins, or that these compounds, at these levels, would have superior BTG reducing effects. It is only based on the disclosure of the present application that one of ordinary skill in the art would know to select specific varieties of tea, i.e. those with high levels of the recited methylated catechins at the recited levels, for the unexpected result of lowering BTG levels. Thus, the claims cannot be obvious in view of the cited combination of references.

## No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

#### CONCLUSION

Applicants submit that all claims are in condition for allowance. However, if minor matters remain, the Examiner is invited to contact the undersigned at the telephone number provided below. If any additional fees are required, please charge these to Deposit Account No. 11-1410. Should there be any questions concerning this application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Datada

By:

Neil S. Bartfeld, Ph.D.

Agent of Record

Registration No. 39,901

Customer No. 20,995

(619) 235-8550